

CLAIMS

1. Stabilising formulation for polyclonal immunoglobulins G compositions, characterised in that the formulation includes a
5 sugar alcohol, glycine in a concentration between 7 g/l and 10 g/l and a non-ionic detergent in a concentration between 20 and 50 ppm, in order to be suitable for the stabilisation of immunoglobulins G compositions in liquid form and in lyophilised form.
- 10 2. Stabilising formulation according to claim 1 consisting of the said sugar alcohol, glycine and non-ionic detergent.
3. Formulation according to claim 1, characterized in that the sugar alcohol is mannitol.
- 15 4. Formulation according to claim 3, characterized in that the concentration of mannitol is between 30 g/l and 50 g/l.
5. Polyclonal immunoglobulins G composition in liquid form comprising, as stabiliser,
20 a stabilising formulation consisting of a sugar alcohol, glycine in a concentration between 7 g/l and 10 g/l and a non-ionic detergent in a concentration between 20 and 50 ppm.
6. Polyclonal immunoglobulins G
25 composition in lyophilised form, obtained by lyophilisation of a polyclonal immunoglobulins G composition and a stabilising formulation including a sugar alcohol, glycine in a concentration between 7 g/l and 10 g/l and a non-ionic detergent in a
30 concentration between 20 and 50 ppm.
7. Polyclonal immunoglobulins G composition according to claim 5, characterized in that it includes an amount of polymers less than 0.3 % after a 6 months storage period at room
35 temperature.
8. Polyclonal immunoglobulins G

composition according to claim 6, characterized in that it includes an amount of polymers less than 0.3 % after a 12 months storage period at room temperature or for 6 months at 40°C.

5 9. Polyclonal immunoglobulins G
composition according to claim 5, characterized in that the composition includes an amount of dimers less than 7 % after a 24 months storage period at 4°C.

10 10. Use of a stabilising formulation according to claim 2 as stabiliser, for polyclonal immunoglobulins G compositions in liquid form obtained directly by fractioning of human plasma.

15 11. Use of a stabilising formulation according to claim 1, for stabilisation of polyclonal immunoglobulins G compositions in lyophilised form.

20 12. Use of a stabilising formulation according to claim 1 for stabilisation of polyclonal immunoglobulins G compositions in liquid form obtained after reconstitution in a suitable aqueous medium of polyclonal immunoglobulins G compositions in lyophilised form.